

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Docket No. 15-IS-5713 (13033US01)

In the Application of:

Thanos Karras

Serial No.: 09/681,306

Filed: March 15, 2001

For: INTEGRATION OF MOBILE
IMAGING UNITS INTO AN
APPLICATION SERVICE
PROVIDER FOR DATA STORAGE
AND INFORMATION SYSTEM
SUPPORT

Examiner: Bleck, Carolyn M.

Group Art Unit: 3626

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Sir or Madam:

This Reply Brief responds to the Examiner's Answer mailed on January 24, 2007. The Applicant respectfully requests that the Board of Patent Appeals and Interferences reverse the final rejection of claims 1, 3-9, 11-14, 16-17 and 19-36 of the present application.

REMARKS

In response to Applicant's Appeal Brief, the Examiner states the following:

It is noted that an "ultrasound system" having wheels as is shown in Figure 2 [of the Wood '035 patent] is a "mobile facility" that is capable of being moved to a plurality of locations[.]¹

As per claim 17, Appellant's Background of the Invention discloses a remotely accessible application service provider (ASP) system (page 2, par. 5) comprising:

(a) a data center including at least one application, said data center including computing power for accessing applications (pages 2-3, par. 5-6); and

(b) a mobile imaging unit wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations (pages 1-2, par. 2-4).²

Applicant respectfully disagrees with the Examiner's characterization. Applicant's arguments focus on the following:

- (1) The ultrasound cart of the Wood '035 patent is not a mobile facility as recited in the pending claims and defined in the present application and clearly does not teach or suggest, alone or in combination with the other cited references, the mobile imaging facility presently claimed.
- (2) Applicant's Background of the Invention identifies needs and deficiencies in existing systems and methods, but does not admit that claimed systems and methods addressing those needs and deficiencies are prior art.

1. Wood Does Not Teach Or Suggest A Mobile Imaging Unit, Wherein Said Mobile Imaging Unit Is A Mobile Facility Adapted To Be Used At A Plurality Of Locations

¹ See Examiner Answer at pages 4, 7, 9-10, 16-17, 19 and 21.

² See *id.* at page 12.

The present application describes a mobile imaging unit as follows:

Many healthcare facilities, such as hospitals and clinics, employ mobile imaging units to facilitate medical examination of patients. **Mobile imaging units may include equipment for MR (magnetic resonance), CT (computerized tomography), and the like, to facilitate medical examination of patients.** Because hospitals and clinics may not have adequate facilities or funding to handle all patients and examinations, hospitals and clinics may hire or purchase mobile imaging units to help perform medical diagnostic examinations, for example MR and CT imaging. **The use of mobile imaging units helps to reduce patient overflow problems by providing healthcare facilities with additional resources for patient examination.** Additionally, the use of mobile imaging units may provide access to technologically advanced imaging solutions on a cost-effective basis.

A typical mobile imaging unit may be scheduled among multiple healthcare facilities. **Mobile imaging units (typically large trucks or vans) are usually positioned outside the healthcare facility.** A patient may be sent from the hospital or clinic to the mobile unit. **An image may be taken of a patient (such as a MR or CT image) in the mobile unit. Currently, the patient image is manually processed in the mobile unit.** Commonly, the image is either printed on film or stored on media such as a floppy disk, CD-ROM, and the like. **The stored image is typically manually transported (often called “sneaker net” in the art) from the mobile imaging unit to the hospital or clinic where the image may be further processed or stored.** Alternatively, some mobile imaging units and hospitals transmit images from a mobile unit to a hospital or clinic via a cable network connection (such as an Ethernet connection in the parking lot).³

As described above, communication between a mobile unit and a PACS at a location may be difficult. Additionally, data taken at any one facility is typically stored in a PACS at that facility and is not available elsewhere. The localization of data at a single facility presents problems in mobile use because of limitations on data access and availability. Thus, it may be advantageous for mobile imaging units to be able to centrally archive images and data. **Today, data collection is performed using either sneaker-net (manual file transfer by disk or manual transfer of film) or via a physical wire-based network connection to the main facility (such as by a network connection in a hospital parking lot for the mobile imaging unit).** Furthermore, data collection is done locally on a facility-by-facility basis.⁴

³ See, e.g., Application, at pages 1-22.

⁴ See *id.* at page 4.

As an example, a medical diagnostic examination of a patient is performed at the mobile imaging unit 120, and a resulting medical diagnostic image is obtained. Then, the mobile imaging unit 120 accesses the data center 110 via the mobile imaging unit/data center communication interface 130. Next, the mobile imaging unit 120 stores the medical diagnostic image at the data center 110. Storage and access of data occurs independent of the locations of the mobile imaging unit 120 and the data center 110.⁵

The healthcare facility 240 is preferably a hospital, a medical clinic, a doctor's office, some other medical office, or any other terminal, for example. **The healthcare facility 240 may include medical diagnostic imaging equipment, such as MR imaging equipment, CT imaging equipment, and/or ECG equipment, as examples. The healthcare facility 240 may also include patient treatment equipment, such as first aid equipment, cardiac support equipment, and/or life support equipment, for example.**⁶

From the specification and the claims, it is clear that the mobile imaging unit is a mobile facility that **includes** medical diagnostic equipment, such as MR (magnetic resonance) imaging equipment, CT (computerized tomography) imaging equipment, and/or ECG (electrocardiogram) equipment, as examples.⁷ The mobile imaging unit may also **include** paramedic equipment, such as first aid equipment, cardiac equipment, and/or life support equipment, for example.⁸ The equipment included in the mobile imaging unit could definitely include the wheeled ultrasound cart of the Wood '035 patent, but the mobile imaging unit as described in the present application is clearly different and patentably distinct from the wheeled ultrasound cart of Wood '035.

The mobile imaging unit is defined in the specification as a mobile imaging facility, for example a truck or van, that may be positioned outside a healthcare facility.⁹ The mobile imaging unit facilitates medical diagnostic examination of a patient (for example, an MR or CT scan).¹⁰ The healthcare facility and the mobile imaging unit are defined as two examples of imaging facilities.¹¹ Data from the medical diagnostic

⁵ See *id.* at page 8.

⁶ See *id.* at page 10.

⁷ See, e.g., Application, at page 3, paragraph 30.

⁸ *Id.*

⁹ See, e.g., Application, at page 1, paragraph 3.

¹⁰ See, e.g., Application, at page 3, paragraph 31.

¹¹ See *id.* at page 17.

examination (for example, an image) is transmitted to the data center via the mobile imaging unit/data center communication interface.¹² The data center may store the examination data for later retrieval by the mobile imaging unit or other entity.¹³ Additionally, the medical imaging unit may access medical applications via the data center.¹⁴

As shown in Fig. 2, the ultrasound system of Wood '035 is illustrated on a mobile cart. The ultrasound system of Wood '035 is not a *mobile facility* adapted to be used at a plurality of locations, as recited in claim 21, as amended in the Office Action Response of Feb. 8, 2006.¹⁵ Wood '035 does not teach or fairly suggest at least “a mobile imaging unit including medical imaging equipment, wherein said mobile imaging unit is *a mobile facility* adapted to be used at a plurality of locations.” Rather, Wood '035 simply discloses the medical imaging equipment that can be *included* in the mobile imaging facility. Even though the ultrasound system may have wheels, it is still medical imaging equipment and not a mobile facility including medical imaging equipment. Additionally, Wood '035 does not disclose “a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center” for at least the reason that Wood '035 simply does not disclose a mobile imaging unit as recited in claim 21.

The Examiner seems to impart great meaning to the use of “e.g.,” “may” and “for example.” The Examiner appears to suggest that by providing several examples or alternatives the Applicant fails to define and describe his invention. Applicant submits that this is incorrect and without basis in statutory or case law or USPTO regulation. In fact, as illustrated in MPEP 2165, there is no statutory requirement for the disclosure of a specific example or for the applicant to point out or highlight which of their embodiments they consider to be their best mode. Simply including that embodiment is sufficient.

To satisfy the requirements of 35 U.S.C. 112, the Applicant must provide a written description of the invention to enable any person skilled in the art to make and

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ The Office Action Response filed on February 8, 2006, is attached as Evidence Appendix D.

use the invention. 35 U.S.C. 112 ¶ 1. The specification shall also set forth the best mode contemplated by the inventor of carrying out his or her invention. *Id.* The statute makes no requirement that a best mode must be highlighted or stated as “required”, only that the best mode be sufficiently set forth. *Id.* Therefore, the Applicant respectfully submits that the Examiner’s interpretation of 35 U.S.C. 112 and her construction of the term “mobile imaging unit” as set forth in the patent specification and claims, and as discussed in the prosecution history, is incorrect. *See* June 14, 2006 Amendment and Response at page 14. A description of various embodiments and various alternatives is sufficient description of the meanings of mobile imaging units, and the Applicant is entitled to at least those disclosed embodiments and their equivalents. The claims are to be interpreted in light of the specification, and the Applicant is entitled to be his or her own lexicographer in defining and describing the claimed terms. The meaning of the term “mobile imaging unit” is clear in the specification to a person skilled in the art, and the Examiner should fairly rely on that meaning in interpreting the claims in view of the prior art. *See, e.g.*, MPEP 6801.01(o).

Furthermore, the meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. MPEP 2173.05(a). Here, the meaning of the term “facility” is clear from the specification. The specification describes the mobile imaging unit as including medical and other equipment, such as the imaging equipment described in Wood ‘035. The specification discusses the mobile imaging unit as a mobile extension of a healthcare facility, designed to take some of the burden and patient load away from the healthcare facility and designed to be mobile such that it can travel between healthcare facilities.¹⁶ No one is getting into, being examined in or traveling in the wheeled ultrasound cart of Wood ‘035.

Additionally, contrary to the Examiner’s assertion that the limitations discussed are not recited in the claim, Applicant points out that the claims have been amended to affirmatively recite that the mobile imaging unit is in fact a mobile facility. The limitation is clearly in the claim and is defined in the specification such that it clearly excludes a standalone piece of imaging equipment, such as a wheeled cart, and rather

¹⁶ *See, e.g.*, Application at pages 17-18.

focuses on a vehicle providing mobility to imaging and other equipment for use in examination of patients at multiple locations. Reading the rest of the claim, the mobile imaging facility communicates with a data center, rather than isolated PACS systems, via a connection, rather than relying upon the current sneaker-net or manual, local delivery system. Furthermore, looking to the ordinary and customary meaning of “facility”; Merriam-Webster’s Medical Dictionary defines a facility as “something (as a hospital) that is built, installed, or established to serve a particular purpose.”¹⁷ The American Heritage Dictionary defines a facility as “something created to serve a particular function: *hospitals and other health care facilities*.”¹⁸ Dictionary.com defines a facility as “something designed, built, installed, etc., to serve a specific function affording a convenience or service: *transportation facilities; educational facilities; a new research facility*.”¹⁹

Thus, Applicant is not asking the Examiner to provide special meaning to the term “mobile facility” or “mobile imaging facility” by extending it to a cart with wheels. Instead, Applicant is asking the Examiner to interpret a mobile facility as it has been defined and used in the specification. Applicant submits that this is commensurate with what one of ordinary skill in the art would understand a mobile facility to be, viewing the specification and in light of the standard dictionary definitions highlighted above. Such a mobile facility for medical imaging is neither taught nor suggested by the Wood ‘035 patent or any other cited reference used by the Examiner in rejecting the pending claims.

2. Applicant’s Background Of The Invention Identifies Needs And Deficiencies In Existing Systems And Methods But Does Not Admit That Claimed Systems And Methods Addressing Those Needs And Deficiencies Are Prior Art.

In the Final Office Action of April 14, 2006, the Examiner rejected claims 17 and 19-20 under 35 U.S.C. 103(a) as being unpatentable over the Applicant’s Background of the Invention in view of Rothschild. With regard to claims 17 and 19-20, Applicant’s

¹⁷ Merriam-Webster’s Medical Dictionary, 2000 edition.

¹⁸ American Heritage Dictionary, Fourth Edition, 2000 (emphasis in original).

¹⁹ Dictionary.com Unabridged (v 1.1), based on the Random House Unabridged Dictionary, 2006 (emphasis in original).

Background identifies a problem that had yet to be solved and a combination that had yet to be realized in the art. However, the Examiner asserts that Applicant's Background of the Invention admits that substantial elements of the claims are prior art and can be obviously combined with Rothschild to suggest the limitations of claims 17 and 19-20. However, upon review, this is clearly not the case. The Applicant's Background addresses deficiencies which are remedied by the Applicant's novel solution and not by Rothschild. *See* June 14, 2006 Amendment and Response at pages 12-13.

As discussed in the Background section of the present application, current systems at the time of the present invention were not remotely accessible, were not centralized, and did not include a medical application service provider system. The Applicant notes that "[t]here is a **need** for centralized data storage to enable the patient's choice of hospital or clinical location." (emphasis added.) This is a need that the Applicant is attempting to satisfy with his invention. Furthermore, "[t]here is a **need** for a method of aggregating patient imaging results from mobile imaging units to eliminate manual transfer of files and to facilitate interaction among mobile units and between mobile units and healthcare facilities." (emphasis added.) This was a need the Applicant saw and was trying to meet. Centralized scheduling and reporting was another need that was unmet with mobile imaging units that the Applicant identified. "Thus, a **need** exists for a method and apparatus for integration of mobile imaging units into an Application Service Provider for data storage and information system support." (emphasis added.) The Applicant's Background of the Invention and the Rothschild patent fail to disclose the novel combination of these elements, which satisfy an unmet need for centralized accumulation and storage of medical data and applications from mobile imaging units to remedy the localized and/or manual nature of prior systems. While mobile imaging units were discussed in the Background (although not in Rothschild, Wood, or any of the other references), the particular use and configuration of the mobile imaging units recited in claims 17 and 19-20 were not disclosed. Additionally, the medical application center of claims 17 and 19-20 was not disclosed in the Background, Rothschild or other references.

Clearly these statements were not admissions of prior art but, conversely, were highlighting problems and/or deficiencies which existed and for which remedies have been found in various embodiments of the invention described in the remainder of the

patent application. Thus, the Applicant illustrates a need for solutions that are then described in the present application. The Applicant's statements of needs or deficiencies should not be construed as admissions of prior art.

As indicated in the Applicant's Background, this was a need that no one had solved. Rothschild mentions nothing of a medical application center, a mobile imaging unit, etc. to provide a remotely accessible centralized medical application service provider system. Therefore, the system of claims 17 and 19-20 is neither taught nor suggested by Rothschild or any combination of Rothschild with the other cited art or the Applicant's Background of the Invention. "[T]he prior art reference (or references when combined) must teach or suggest all the claim limitations."²⁰

"The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure."²¹ The Examiner, however, offers no support from the references for his conclusions regarding motivation to combine. In short, the Examiner's rationale for a motivation to combine the references amounts to no more than a conclusory statement of convenient assumptions about one of ordinary skill in the art, which is a factual question that cannot be resolved on "subjective belief and unknown authority."²²

"The factual inquiry whether to combine references must be thorough and searching."²³ "It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."²⁴ The Examiner does not base his conclusions on any evidence of record (i.e., the cited references). Instead, the Examiner summarily concludes, without any prior art evidence, that one would be motivated to combine various references. Federal Circuit "case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or

²⁰ See Manual of Patent Examining Procedure (MPEP) at § 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

²¹ See Manual of Patent Examining Procedure (MPEP) at § 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

²² See *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002).

²³ See, e.g., *McGinley v. Franklin Sports, Inc.* 262 F.3d 1339, 1351-52 (Fed. Cir. 2001).

²⁴ See *In re Lee*, 277 F.3d at 1343 (internal citations omitted).

motivation to combine prior art references.”²⁵ The “examiner can satisfy the burden of showing obviousness of the combination ‘only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching reference.’”²⁶ The Examiner clearly has not offered any objective teaching to support his assertions regarding motivation to combine. Instead, the Examiner offers only subjective opinion as support.

In *In re Lee*, the Federal Circuit noted that “Board rejected the need for ‘any specific hint or suggestion in a particular reference’ to support the combination of ... references,” which was an “[o]mission of a relevant factor required by precedent” that was both “legal error and arbitrary agency action.”²⁷ The Examiner has not specified any hint or suggestion in the cited references to support their combination.

[The Federal Circuit] explained ... that “deficiencies of the cited references cannot be remedied by the Board’s general conclusions about what is ‘basic knowledge’ or ‘common sense.’” The Board’s findings must extend to all material facts and must be documented in the record, lest the “haze of so-called expertise” acquire insulation from accountability. “Common knowledge and common sense,” even if assumed to derive from the agency’s expertise, **do not substitute for authority when the law requires authority.**”²⁸

The Examiner’s subjective opinion of “common knowledge” or “common sense” regarding a motivation to combine is not enough to establish a *prima facie* case of obviousness. Thus, at least for these reasons, Applicant respectfully submits that the pending claims should be in condition for allowance.

²⁵ *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

²⁶ *See in re Lee*, 277 F. 3d at 1343, citing *In re Fitch*, 972 F. 2d 1260, 1265 (Fed. Cir. 1992) (emphasis added).

²⁷ *See id.* at 1344, citing *Morot Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 at 43 (1983).

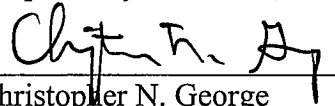
²⁸ *See id.* at 1344-1345 (internal citations omitted).

CONCLUSION

For the foregoing reasons, claims 1, 3-9, 11-14, 16-17 and 19-36 are distinguishable over the prior art of record. Thus, the Applicant respectfully requests a reversal of the Examiner's rejection and issuance of a patent on the present application. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to the deposit account of GEMS-IT, Account No. 502401.

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CLAIMS APPENDIX

The following claims are involved in this appeal:

1. A remotely accessible centralized medical information system, said system comprising:

a mobile imaging unit for generating medical data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

at least one data retriever for retrieving data from a data center; and

a data center for storing data, said data center accessible from said at least one data retriever, said at least one data retriever located at at least one distinct geographic retrieval point.

2. (Cancelled)

3. The system of claim 1, wherein said data retriever comprises a mobile imaging unit.

4. The system of claim 1, wherein said data retriever comprises a healthcare facility.

5. The system of claim 1, further including a healthcare facility, wherein said healthcare facility is adapted to generate medical data storable in said data center.

6. The system of claim 1, wherein said data center comprises an application service provider.

7. The system of claim 1, wherein said mobile imaging unit generates medical images.

8. The system of claim 1, wherein said mobile imaging unit generates medical reports.

9. A centralized medical information system, said system comprising:

a mobile imaging unit for generating data storable in a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said mobile imaging unit.

10. (Cancelled)

11. The system of claim 9, wherein said data generator comprises further including a healthcare facility, wherein said healthcare facility is adapted to generate data storable in said data center.

12. The system of claim 9, wherein said data center comprises an application service provider.

13. A centrally accessible medical information system, said system comprising:

a mobile imaging unit for retrieving data from a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

a data center for storing data, said data center geographically distinct from said mobile imaging unit.

14. The system of claim 13, wherein said data retriever comprises further including a healthcare facility, wherein said healthcare facility is adapted to retrieve data from a data center.

15. (Cancelled)

16. The system of claim 13, wherein said data center comprises an application service provider.

17. A remotely accessible centralized medical application service provider system, said system comprising:

a medical application center including at least one medical application, said medical application center including processing power for accessing said medical application; and

a mobile imaging unit, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations, said mobile imaging unit accessing the output of said medical application.

18. (Cancelled)

19. The system of claim 17, further including a healthcare facility, wherein said healthcare facility is adapted to access the output of said medical application.

20. The system of claim 17, wherein said medical application center also stores administrative applications.

21. A remotely accessible centralized data storage system for mobile medical imaging, said system comprising:

a mobile imaging unit including medical imaging equipment, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center storing medical information in electronic form; and

a mobile imaging unit/data center communication interface allowing medical information to be transmitted between said mobile imaging unit and said data center.

22. The system of claim 21, further comprising a healthcare facility and a healthcare facility/data center communication interface allowing medical information transmission between said data center and said healthcare facility.

23. The system of claim 22, further comprising an authentication module for authorizing access to said data center from at least one of said healthcare facility and said mobile imaging unit.

24. A method for remotely storing medical information, said method comprising:

transmitting medical information collected from a patient at a mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and
storing said medical information at said data center.

25. The method of claim 24, wherein said step of storing includes authenticating access to said data center.

26. The method of claim 24, further comprising the step of retrieving said medical information from said data center.

27. The method of claim 26, wherein the step of retrieving includes authenticating access to said data center.

28. A method of communicating between a mobile imaging unit and a healthcare facility, said method comprising:

transmitting information from said mobile imaging unit to a data center, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

retrieving said information from said data center at said healthcare facility.

29. A system for communication between a mobile imaging unit and a healthcare facility, said system comprising:

a mobile imaging unit capable of transmitting medical diagnostic information, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations;

a data center capable of receiving said medical diagnostic information, storing said medical diagnostic information, and transmitting said medical diagnostic information; and

a healthcare facility capable of accessing said medical diagnostic information from said data center.

30. The system of claim 29, wherein said data center is further capable of storing medical applications and executing medical applications.

31. The system of claim 30, wherein said mobile imaging unit is further capable of executing medical applications via said data center.

32. The system of claim 30, wherein said healthcare facility is further capable of executing medical applications via said data center.

33. A method for remotely accessing medical information, said method comprising:

accessing a data center from a mobile imaging unit at a remote location, wherein said mobile imaging unit is a mobile facility adapted to be used at a plurality of locations; and

retrieving medical information from said data center.

34. The method of claim 33, wherein said step of accessing includes authenticating access to said data center.

35. The method of claim 28, further comprising remotely analyzing said information at said data center via at least one of said mobile imaging unit and said healthcare facility.

36. The method of claim 28, further comprising aggregating data from a plurality of geographic locations at said data center using at least one of said mobile imaging unit and said healthcare facility.